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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,369	06/28/2000	John R. Stuelpnagel	A-67493-3/DJB/RMS/DCF	6020
29389	7590	11/18/2005	EXAMINER	
ILLUMINA, INC. 9885 TOWNE CENTRE DRIVE SAN DIEGO, CA 92121-1975			BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	
DATE MAILED: 11/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/606,369	Applicant(s) STUELPNAGEL ET AL.	
	Examiner William H. Beisner	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al.(US 4,879,097) in view of Kolehmainen et al.(US 4,349,510) and Tajima et al.(US 5,682,232).

The reference of Whitehead et al. discloses a device for forming a chamber which includes a base plate (10, 11) which holds a microtiter plate (16, 17). The device includes a lid including component ports for immobilizing array components (28 or 350). The device includes sealant (21) between the base and the lid.

While the reference of Whitehead et al. discloses sealant, 21, so as to seal the chamber to prevent entry of stray light (See the abstract), the instant claims recite that the sealant provides an "airtight" seal.

The reference of Kolehmainen et al. discloses an optical analysis system which detects chemiluminescence. The reference of Kolehmainen et al. discloses that a light-tight seal can be maintained using an o-ring, 38 (See column 4, lines 6-27). The light-tight seal prevents external light from interfering with the detector.

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ an o-ring seal in place of seal, 21, in device of Whitehead et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, sealing the interior of the reaction region from exterior light. Use of an o-ring as suggested by the reference of Kolehmainen et al. would inherently result in an airtight seal. Furthermore, the use of an o-ring to form the light-tight seal of Whitehead et al. would be advantageous over the seal (21) of

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Whitehead et al. because the o-ring would also provide an air-tight seal that would provide better contamination protection with respect to contaminants entering the reaction chamber.

While the combination of the references of Whitehead et al. and Kolehmainen et al. suggests the use of an o-ring-type of seal for creating a light-tight seal, the instant claims further differ by reciting that the device includes “a clamp providing increased pressure between said lid and said base plate”.

The reference of Tajima et al. discloses that when forming a light-tight seal between a base plate (9) and a lid (5) it is known in the art to employ an elastic sealing member (See column 4, lines 43-53). The reference also discloses the use of a clamping device (8) for increasing the pressure between the lid (5) and the base plate (9).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of the modified primary reference with a clamp device for the known and expected result of providing an art recognized means for comprising an elastic sealing member, such as an o-ring, so as to provide a light-tight seal with respect to the lid and base plate of the detection housing.

With respect to claim 29, the lid of the device of Whitehead et al. includes openings or ports that include second array components (28, 129, 228).

With respect to claim 30, the first array component is a microtiter plate (16,17).

With respect to claim 31, the references of Whitehead et al. and Kolehmainen et al. discloses that is it known in the art to monitor chemiluminescent or bioluminescent reactions performed in microtiter plate arrays using an array of fiber optic devices (See Column 4, lines 61-66 of Whitehead et al. and Figure 4 of Kolehmainen et al.).

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In view of these teachings and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a fiber optic array in the lid structure of the reference of Whitehead et al. for the known and expected result of providing an alternative means recognized in the art to detect chemiluminescent reactions. Provision of the fiber optic and electrical detection system would provide increased reliability over the use of photographic film which is analyzed visually and/or provide an additional analytical techniques simultaneously.

With respect to claims 32 and 33, the device includes male/female alignment means (22).

With respect to claims 34 and 35, as shown in Figure 11, the chamber is connected to at least one fluid-handling device (350).

5. Claims 36-51 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al.(US 4,879,097) in view of Kolehmainen et al.(US 4,349,510) and Tajima et al.(US 5,682,232) taken further in view of Walt et al.(US 6,327,410).

The combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al.(US 5,682,232) has been discussed above.

With respect to claims 36-40, the above claims differ by reciting that the second array component of the lid includes arrays of bioactive agents, specifically, a substrate that includes discrete sites containing a microspheres of distinctive bioactive agents.

The reference of Whitehead et al. discloses that the disclosed supports (129) can take the form of fiber optic sensors (See column 9, lines 61-66).

The reference of Walt et al. discloses that the use of a substrate including discrete sites and a population of microspheres comprising first and second subpopulations distributed on the discrete sites wherein each subpopulation includes a distinct bioactive agent is known in the art (See column 4, line 35, to column 5, line 31).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the fiber optic sensor devices disclosed in the reference of Walt et al. in the system of the reference of Whitehead et al. for the known and expected result of providing a means recognized in the art for contacting a fiber optic sensor with a sample for analyte detection. Advantages of using the fiber optic sensor of Walt et al. over other prior art sensors include the ease of manufacture and the ability to perform high density screening of samples. Use of the system of Whitehead et al. for contacting the fiber optic sensor with a sample of analyte would allow a plurality of samples to be simultaneously contacted with a plurality of separate fiber optic sensors while maintaining a light-tight environment.

With respect to claim 41, it would have been obvious to one of ordinary skill in the art to coat each support (129) with a different bioactive agent for the known and expected result of providing a means for simultaneously performing a plurality of different luminescent immunospecific assays.

With respect to claims 42 and 43, the reference of Walt et al. discloses the claimed density of bioactive agents (See column 5, lines 4-23).

With respect to claims 44 and 45, while the reference of Whitehead et al. employs a 6x10 array of wells, it would have been obvious to one of ordinary skill in the art to modify the system to employ any of the standard microplate formats known in the art.

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With respect to claims 46 and 47, the device includes male/female alignment means (22).

With respect to claim 48, as shown in Figure 11, the chamber is connected to at least one fluid-handling device (350).

With respect to claims 36, 49 and 50, the reference of Walt et al. discloses the use of subpopulations and/or random array of microspheres.

With respect to claim 51, the reference of Walt et al. discloses list of possible bioactive agents (See column 7, line 55, to column 8, line 67) that includes peptides and nucleic acids.

With respect to claims 53-55, when using the random array of microspheres as suggested by the reference of Walt et al., the sample holding or assay location microplate would include a plurality of analytes. Furthermore, the reference of Walt et al. discloses that it is known to fluorescently label the target analytes (See column 21, lines 17-25).

With respect to claim 56, the first array component is a microwell plate and not a fiber optic array.

6. Claim 52/29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al.(US 4,879,097) in view of Kolehmainen et al.(US 4,349,510) and Tajima et al.(US 5,682,232) taken further in view of Heffelfinger et al.(US 5,784,152).

The combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al.(US 5,682,232) has been discussed above.

Claim 52 differs by reciting that the device further includes a heating device.

The reference of Heffelfinger et al. discloses that it is conventional in the art to provide a system for optically monitoring chemical reactions within a microplate with a temperature controlled incubator (102).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of the modified primary reference with a device for controlling the temperature during the reaction for the known and expected result of ensuring that the proper temperature is maintained during the optical monitoring of the reaction. Note the temperature control device would inherently include a heating device. The temperature maintained within the device would have been merely based on the specifics of the reaction that is to be monitored within the device.

7. Claims 52/37,38,39 or 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al.(US 4,879,097) in view of Kolehmainen et al.(US 4,349,510), Tajima et al.(US 5,682,232) and Walt et al.(US 6,327,410) taken further in view of Heffelfinger et al.(US 5,784,152).

The combination of the references of Whitehead et al., Kolehmainen et al. Tajima et al. and Walt et al. has been discussed above.

Claim 52 differs by reciting that the device further includes a heating device.

The reference of Heffelfinger et al. discloses that it is conventional in the art to provide a system for optically monitoring chemical reactions within a microplate with a temperature controlled incubator (102).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system of the modified primary reference with a device for controlling the temperature during the reaction for the known and expected result of ensuring that the proper temperature is maintained during the optical monitoring of the reaction. Note the temperature control device would inherently include a heating device. The temperature maintained within the device would have been merely based on the specifics of the reaction that is to be monitored within the device.

Response to Arguments

8. With respect to the rejection of claims 29-35 under 35 USC 103 over the combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al., Applicants' argue (See pages 7-9 of the response filed 8/22/05) that the rejection is improper for the following reasons:

a) If the light sealing properties of the o-ring are equivalent to those of the rib of Whitehead et al., then there would not have been any motivation to include a clamp. One of ordinary skill in the art would not have been motivated to add a clamp to an already satisfactorily modified device. Applicants stress that the mere fact that the references can be combined is not proper unless the prior art suggests the desirability of the combination.

b) Applicants argue that that an o-ring with a clamp is not equivalent to an o-ring without a clamp. Applicants stress that the use of an o-ring with a clamp would require further manipulation of the chamber that would be create unwanted shaking of the chamber of Whitehead et al.

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c) The cited prior art does not provide any motivation to make an airtight seal.

Applicants stress that the prior art is silent as to the fact that an o-ring would provide better contamination protection.

d) With respect to new claim 53, there is no suggestion to modify the device of Whitehead et al. to include target analytes having a fluorescent label.

In response to argument a) above, the Examiner is of the position that one of ordinary skill in the art when presented with the disclosures of the prior art references would have clearly recognized that an o-ring is an art recognized equivalent for maintaining a light-tight seal since the rib of Whitehead et al. is provided for providing a light-tight seal and the reference of Kolehmainen et al. as well as the reference of Tajima et al. both disclose the use of o-rings or gasket-like members for providing a light-tight seal. Note an express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). With respect to the use of a clamp for providing increased pressure, while the reference of Kolehmainen et al. does not specifically disclose the use of a clamp per se, the reference shows that the o-ring is moved or forced in a vertical direction to make contact with the opposing surface to create a light-tight seal (See column 3, lines 11-13). Furthermore the reference of Tajima et al. clearly conveys to one of ordinary skill in the art that it is known in the art to create a light-tight seal using a gasket-like member (urethane sponge) and a clamping device (8). Again, in view of these disclosures, one of ordinary skill in the art would have clearly recognized that an o-ring and clamp configuration are known in the art for creating a light-tight seal.

In response to argument b) above, for reasons set forth immediately above, the Examiner is of the position that an o-ring and an o-ring with a clamp are one in the same. Both the references of Kolehmainen et al. and Tajima et al. disclose a vertically applied force for contacting the o-ring or gasket with the opposing surface to create a light-tight seal. As for the unwanted shaking, the Examiner is of the position that this argument is unfounded because it would appear that one of ordinary skill in the art would recognize that the light-tight seals of the references of Kolehmainen et al. and Tajima et al. are made without shaking of the sample holders since contamination between the sample wells would result. Applicants' position as to the state of the level of skill in the art appears to require that the references specifically state that the rib of Whitehead et al. can be replaced with an o-ring and clamp for creating a light-tight seal.

In response to argument c) above, while the prior art does not specifically disclose that use of an o-ring would be advantageous because of improved protection from contamination, the Examiner is also of the position that one of ordinary skill in the art would recognize this advantage. Furthermore use of an o-ring and clamp as suggested by the prior art would inherently result in the formation of an air-tight seal since this is an intrinsic property of an o-ring sealing device.

In response to argument d) above, this new claim limitation has been addressed in the combination of the references of Whitehead et al., Kolehmainen et al., Tajima et al. and Walt et al.

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9. With respect to the rejection of claims 36-51 under 35 USC 103 over the combination of the references of Whitehead et al., Kolehmainen et al., Tajima et al. and Walt et al., Applicants argue (See pages 9-11 of the response filed 8/22/05) that the rejection is improper because the reference of Walt et al. does not cure the deficiencies associated with the combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al. and discussed at length previously. With respect to new claims 54 and 55, Applicants argue that none of the references of Whitehead et al., Kolehmainen et al. and Tajima et al. teach or suggest including a sample solution comprising a plurality of different target analytes having a fluorescent label. Applicants stress that the reference of Walt et al. does not cure the deficiencies of the first three references. With respect to new claim 56, Applicants argue that not of the references in the combination would have motivated one of ordinary skill in the art to make and use a hybridization chamber in which the first array component is not a fiber optic array.

In response, the reference of Walt et al. was not relied upon to provide motivation for replacing a labyrinth seal with an o-ring. The combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al. address this claim limitation. The reference of Walt et al. was relied upon as an additional teaching that addresses the obviousness of employing a second array component wherein each second array component includes "a plurality of different bioactive agents". In response to the comments pertaining to claims 54 and 55, as pointed out in the prior art rejection previous, the reference of Walt et al. provides the motivation of using a sample as claimed in these claims. With respect to the comments concerning claim 56, the first array component in would be the microplate holding the samples and thus it would not be a fiber optic array.

10. With respect to the rejection of claim 52/29 under 35 USC 103 over the combination of the references of Whitehead et al, Kolehmainen et al., Tajima et al. and Heffelfinger et al., Applicants argue (See pages 11-12 of the response filed 8/22/05) that the rejection is improper because the reference of Heffelfinger et al. does not cure the deficiencies associated with the combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al. and discussed at length previously.

In response, the reference of Heffelfinger et al. was not relied upon to provide motivation for replacing a labyrinth seal with an o-ring. The combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al. address this claim limitation. The reference of Heffelfinger et al. was relied upon as an additional teaching that addresses the obviousness of employing a heating device.

11. With respect to the rejection of claim 52/37, 38, 39 or 40 under 35 USC 103 over the combination of the references of Whitehead et al, Kolehmainen et al., Tajima et al., Walt et al. and Heffelfinger et al., Applicants argue (See page 12 of the response filed 8/22/05) that the rejection is improper because the reference of Heffelfinger et al. does not cure the deficiencies associated with the combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al. and discussed at length previously.

In response, the reference of Heffelfinger et al. was not relied upon to provide motivation for replacing a labyrinth seal with an o-ring. The combination of the references of Whitehead et al., Kolehmainen et al. and Tajima et al. address this claim limitation. The reference of

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Heffelfinger et al. was relied upon as an additional teaching that addresses the obviousness of employing a heating device.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

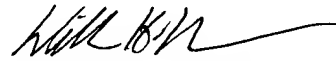
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB